

Applicant: Brodeur et al.
Application Serial No.: 09/723,852
Filing Date: November 28, 2000
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REMARKS/ARGUMENTS

Introduction

The Examiner has rejected claims 1-5, 9-13 and 15-22. Applicant has canceled claims 1, 16-21; amended claims 2-5, 9-13, 15, and 22, and added new claims 23-25. Claims 2-5, 9-13, 15, and 22-25 represent all the currently pending claims in the application. Based on the amended claim and remarks below, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 1-5, 9-13 and 15-22 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains to make and/or use the invention. Specifically, the Examiner rejected claims 1-5, 9-13 and 15-21 because of the terms "non-continuous" and "perimetrically non-continuous".

The rejection has been obviated by the present amendment. Therefore, withdrawal of this rejection is respectfully requested.

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Applicants disagree with the Examiner's interpretation of the specification and claims as failing to adequately describe the terms set forth in the claims. When the specifications, including the drawings is fully considered, the claimed subject matter is clearly described in the specification. Applicants' specification has described what is meant by "perimetrically" and "non-continuous." See p.7-8; Figs. 1-4. This description is sufficient to merit the written description requirement of § 112 first paragraph.

For the sake of advancing the prosecution, however, Applicant has removed these terms from the claims, and substituted non-narrowing language to clarify the scope of the invention.

Additionally, Applicants have canceled claims 1 and 16-18, and amended claims 2-5, 9-13 and 15 to depend from amended claim 22. New claims 23-25 have been added.

Rejection under 35 U.S.C. §112, Second Paragraph

Additionally, the Examiner has rejected claims 1-5, 9-13 and 15-22 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Specifically, the Examiner states:

The meaning of the terms "non-continuous" and "perimetrically non-continuous" is unclear for reasons set forth above.

Rejection is also obviated in view of the present amendment to claims 2-5, 9-13 and 15 and the cancellation of claims 16-21.

The Examiner has rejected claim 22 as lacking antecedent basis for "said continuous body". Applicants have amended claim 22 to include clarifying language having proper antecedent basis.

Applicants believe that the amended claims as they currently stand comply with the requirements of 35 U.S.C. §112, first paragraph and second paragraph. The rejections based therein are therefore overcome. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph and second paragraph, is respectfully requested.

Rejections under 35 U.S.C. §103

The Examiner has rejected claims 1-5, 9-13, 15 and 17 under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0893108 to Ray. The Examiner states:

the reference to "Longitudinally extending strips" in col. 9 lines 18-21 of Ray clearly refers to strips that extend along (parallel to)

the longitudinal axis of the prosthesis since such strips are "Longitudinally extending". Further, the use of this phrase rather than the term "helical" (which is used to describe other embodiments) indicates that a structure other than helical is intended. It would have been obvious that these strips are non-overlapping since the strips shown in the Figures are non-overlapping.

Applicant respectfully traverses the rejection on the grounds that the Examiner has failed to demonstrate a *prima facie* case of obviousness. No where does Ray suggest generally parallel, separate and independent strips. Ray's reference to "longitudinally extending strips of ribbon" is very general at best and fails to provide any direction, other than these strips must satisfy Ray's purpose to be operable. Ray's intent and purpose is to provide increased flexibility, increased kink resistance and reduced shear when his device is longitudinally bent. (Col. 4 lines 10-13; Col. 7 lines 32-37). Thus, as shown in Fig. 2, Ray's invention includes stress relief zones (24) which provides increased flexibility and absorbs stress when bent along its longitudinal axis and resists kinking (col. 4, lines 5-13; col. 8. lines 1-8). These stress relief zones (24) reduce shear stresses between the stent member and the coupling member when the stent-graft undergoes bending so that tearing of the coupling and/or graft member can be minimized or eliminated (col. 3, lines 20-24; col. 7, lines 5-9). Ray discloses a helical construction which satisfies Ray's intentions because it provides the stress-relief zones as above-discussed, as shown in Fig. 6, (col. 8, lines 13-16; col. 7, line 50 through col. 8, line 3).

Ray fails to state how he can achieve his purpose using longitudinally extending strips which do not have a helical component to them. For example, *in arguendo*, if one modifies Ray to include strips arranged longitudinally instead of helical there would be no stress-relief zones provided. Therefore, when one bends the modified invention longitudinally, one side of the modified invention would have excess graft material which may lead to kinking upon bending the graft. The opposite side of the modified invention would experience excessive force, pulling longitudinally along the strips which one would expect graft tearing, or breaking to occur. Additionally, the tear strength of the strips limits the flexibility of the modified invention to properties of the strip material. This is directly opposite of Ray's intent and therefore one would not be motivated to modify the invention as above-discussed. Additionally, there would be no expectation of success as the flexibility and durability of the modified invention would be limited to the graft strip material similarly to that of a conventional fully covered graft, of which Ray intended to overcome by providing the stress-relief zones. Therefore, modifying Ray's invention to the presently claimed invention destroys Ray's intent and purpose, because there would be no structure provided to absorb the stress, and provide resistance to kinking when bent along its longitudinal axis. The law is well settled that to modify a reference which destroy its intent and purpose is impermissible.

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The rejection of claim 1 has been obviated by the above amendment. Those remaining claims previously dependent from claim 1 now dependent from amended claim 22. Amended claim 22 requires as a claim element a tubular form to be made from generally parallel, separate and independent strips. Ray's disclosure fails to suggest generally parallel, separate and independent strips. This is likely due to the fact that the use of such a structure would defeat Ray's intent and purpose.

Thus, Examiner's allegations based on the Ray disclosure can only be considered conjecture at best. There is no motivation or reasonable expectation of success to modify Ray to the claimed invention. Ray fails to disclose, teach or suggest the invention as in the amended claims. The Examiner has, therefore, failed to make a *prima facie* case of obviousness. Reconsideration is respectfully requested.

The Examiner has further rejected claims 16, 18 and 21 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,398,803 to Layne et al. More specifically, the Examiner states:

Although only a portion of the Layne body is used to meet the terms of the claims, the claims do not preclude this.

The rejection is respectfully traversed.

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Claims 16, 18 and 21 have been canceled, thereby obviating, the rejection. Moreover, new claims 23 and 25 are patentably distinct over Layne. Layne fails to disclose a graft having a plurality of generally parallel, separate and independent strips arranged nonoverlapping to define a tubular form, as presently claimed. Layne discloses a graft having holes, punchouts and cut-outs (44) as shown in Figure 2 (col. 5, lines 29-30). However, Layne discloses material interconnected around the hole or cut-outs (44). Layne fails to suggest or teach separate strips which form a tubular form without interconnecting material between the strips.

Layne fails to disclose, teach or suggest the present invention as claimed. Withdrawal and reconsideration is respectfully requested.

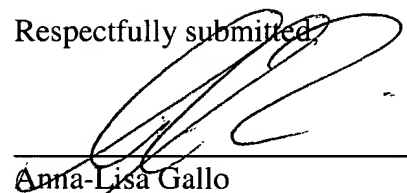
SUMMARY

Applicant respectfully submits that claims 2-5, 9-13, 15 and 22-25 are patentably distinct. The application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

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Should the Examiner have any questions or comments concerning this application or this amendment, he is invited to contact the undersigned counsel.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Anna-Lisa Gallo', is written over a horizontal line.

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